Reviewer's report

Title: NASCITA Italian birth cohort study: a study protocol

Version: 0 Date: 22 Nov 2019

Reviewer: Reviewer 2

Reviewer's report:

PEER REVIEWER ASSESSMENTS:

OBJECTIVE - Full research articles: is there a clear objective that addresses a testable research question(s) (brief or other article types: is there a clear objective)?

No - there are minor issues

DESIGN - Is the current approach (including controls and analysis protocols) appropriate for the objective?

No - there are minor issues

EXECUTION - Are the experiments and analyses performed with technical rigor to allow confidence in the results?

N/A - no experiments or analyses

STATISTICS - Is the use of statistics in the manuscript appropriate?

N/A - there are no statistics in this study

INTERPRETATION - Is the current interpretation/discussion of the results reasonable and not overstated?

Yes - the author's interpretation is reasonable

OVERALL MANUSCRIPT POTENTIAL - Is the current version of this work technically sound? If not, can revisions be made to make the work technically sound?

Probably - with minor revisions
PEER REVIEWER COMMENTS:

GENERAL COMMENTS:

* What is your overall impression of the study?

As said in the protocol, this is large and ambitious birth cohort proposing to check many associations of child development. The protocol proposes to investigate various differences or inequalities in child outcomes in Italy. The authors need to take care on their aims and analysis plan

* What have the authors done well?

The authors have proposed a large important birth cohort study representative of Italy

In what ways does it not meet best practice?

Even though it is in early stage, the authors need to be clear on objectives, corresponding outcome and exposures variables, inclusion criteria, and analysis plan. Some comments regarding these are included below.

REQUESTED REVISIONS:

Abstract

Background: Has NASCITA study been already going on? The present article seems the protocol to conduct the study but the authors claim it was already created.

Methods: If the study is ongoing, why the expected number of newborns, because it sounds like newborns have been already enrolled in the study.

Background:

Even though the study is large and ambitious with broad views, I think that, for particular investigation, it should focus on specific areas. Investigators need to have clear aim.

Hypothesis and significance:

Hypothesis/aims should not be just set as there are differences among geographic areas but how these differences impact upon the outcome (child development) or in which condition the differences will be high or low.
Aims:

There are aims, additional aims and more specific aims. Having said broad views and main purpose of the study, I suggest investigators to have specific aims for the investigation.

At one hand, it seems like the outcome measures are physical, cognitive, and psychological development of child; but again authors have indicated to measure 'nurturing care' (health, nutrition, safety and security, responsive care giving and early learning. So, what are the actual outcome measures and exposure factors? How they will be assessed?

Methods:

Overall, the subtopics in this section are scattered such that the coherent steps or methods of a cohort study are hard to follow. So, there is better way to organise and present this section more logically.

Setting

How a cluster is defined? How the 22 clusters will be selected? What these clusters need to represent? From which areas of Italy?

Recruitment:

Is there a pool of paediatricians in the selected clusters so that you need to sample? Otherwise there are, I suppose, paediatricians assigned in the clusters or health units.

Inclusion and exclusion criteria

There can be inborn defects in some newborns which will affect on development. How will such defects accounted for or excluded in the enrolment?

Analysis plan:

There are so many associations to be tested but I do not see them to match to the specific aims perfectly. The specific aims and analysis plan to answer these aims should match. Another issue, what happens to 'lost to follow up data'.

ADDITIONAL REQUESTS/SUGGESTIONS:

See above my comments.
Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

No

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

No

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

Yes

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

Not relevant to this manuscript

Quality of written English
Please indicate the quality of language in the manuscript:

Acceptable

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